



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	1751.01
True Name	Mycoplasma Gallisepticum Vaccine, Live Culture
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Poulvac Myco F - No distributor specified
Date of Compilation Summary	August 20, 2019

**Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Mycoplasma gallisepticum</i>
<b>Study Purpose</b>	Demonstrate efficacy against <i>Mycoplasma gallisepticum</i> in chickens
<b>Product Administration</b>	
<b>Study Animals</b>	Chicken
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	19 January 1988

<b>Study Type</b>	Efficacy																		
<b>Pertaining to</b>	Mycoplasma gallisepticum																		
<b>Study Purpose</b>	Demonstrate efficacy against Mycoplasma gallisepticum in chickens																		
<b>Product Administration</b>	Eye drop administration																		
<b>Study Animals</b>	96 SPF chickens, 8 weeks of age in two groups: vaccinate and control.																		
<b>Challenge Description</b>	MG-R, 4 weeks post vaccination																		
<b>Interval observed after challenge</b>	Observed for 10 days then evaluated for air sac lesions																		
<b>Results</b>	<p>Efficacy was based on birds with air sac lesions.</p> <table border="1"> <thead> <tr> <th></th> <th colspan="2">Number of Birds</th> <th>Total</th> </tr> <tr> <th>Treatment</th> <th>Positive</th> <th>Negative</th> <th></th> </tr> </thead> <tbody> <tr> <td>Control</td> <td>26</td> <td>22</td> <td>48</td> </tr> <tr> <td>Vaccinates</td> <td>11</td> <td>37</td> <td>48</td> </tr> </tbody> </table> <p>The raw animal data for the animals are shown on the attached pages. Air sac lesions were scored from 0 to 4 and a bird was considered positive if it had a score of 2 or greater.</p>				Number of Birds		Total	Treatment	Positive	Negative		Control	26	22	48	Vaccinates	11	37	48
	Number of Birds		Total																
Treatment	Positive	Negative																	
Control	26	22	48																
Vaccinates	11	37	48																
<b>USDA Approval Date</b>	13 May 2014																		

<b>Treatment Group</b>	<b>Animal Number</b>	<b>Air Sac Lesions</b>	<b>Lesion score positive: lesion score <math>\geq</math> 2; negative: lesion score <math>&lt;</math> 2</b>
Control	151	Negative	1
	152	Negative	1
	153	Negative	1
	154	Negative	0
	155	Negative	1
	156	Positive	2
	157	Negative	1
	158	Positive	4
	159	Negative	1
	160	Positive	3
	161	Positive	3
	162	Negative	1
	163	Positive	4
	164	Positive	3
	165	Negative	0
	166	Positive	2
	167	Positive	2
	168	Positive	3
	169	Positive	3
	170	Negative	1
	171	Positive	3
	172	Positive	2
	173	Positive	2
	174	Positive	3
	175	Negative	1
	201	Negative	1
	202	Negative	1
	203	Negative	1
	205	Negative	1
	206	Positive	2
	207	Positive	2
	208	Negative	1
	209	Negative	1
	210	Positive	2
	211	Positive	3
	212	Negative	0
	213	Positive	2
	214	Positive	3
	215	Positive	2
	217	Negative	0
	218	Positive	4
	219	Positive	3
	220	Positive	2
	221	Negative	0
	222	Positive	3

	223	Negative	1
	224	Negative	1
	225	Positive	3
Vaccinates	176	Negative	0
	177	Negative	1
	178	Negative	0
	179	Negative	0
	180	Positive	2
	181	Negative	0
	182	Negative	0
	183	Positive	3
	184	Positive	2
	185	Negative	0
	186	Negative	0
	187	Negative	0
	188	Positive	2
	189	Negative	1
	190	Negative	0
	191	Positive	2
	192	Negative	1
	193	Positive	3
	194	Negative	1
	195	Negative	0
	196	Negative	0
	197	Negative	0
	198	Negative	0
	199	Positive	3
	200	Negative	0
	276	Negative	0
	277	Negative	0
	278	Negative	0
	279	Negative	0
	280	Negative	0
	281	Negative	1
	282	Positive	2
	283	Negative	0
	284	Negative	0
	285	Positive	2
	286	Negative	0
	287	Negative	0
	289	Negative	1
	290	Negative	0
	291	Negative	0
	292	Positive	2
	294	Negative	0
	295	Negative	0
	296	Negative	0
	297	Positive	2
	298	Negative	1

	299	Negative	0
	300	Negative	0

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	Demonstrate safety under field conditions
<b>Product Administration</b>	
<b>Study Animals</b>	Chicken
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	3 February 1988

<b>Study Type</b>	Safety																																			
<b>Pertaining to</b>	ALL																																			
<b>Study Purpose</b>	Demonstrate safety under field conditions																																			
<b>Product Administration</b>	Eye drop																																			
<b>Study Animals</b>	Commercial layer pullets 9 weeks of age																																			
<b>Challenge Description</b>	Not applicable																																			
<b>Interval observed after challenge</b>	Chickens were observed daily for mortality and adverse events for 6 weeks post-vaccination																																			
<b>Results</b>	<p>Results of the Field Safety Study</p> <table border="1"> <thead> <tr> <th></th> <th>Number placed</th> <th>Mortality %</th> </tr> </thead> <tbody> <tr> <td colspan="3"><b>Site 1</b></td> </tr> <tr> <td>Control</td> <td>75,634</td> <td>0.66</td> </tr> <tr> <td>Control</td> <td>107,587</td> <td>0.88</td> </tr> <tr> <td>Control</td> <td>88,553</td> <td>0.88</td> </tr> <tr> <td>Vaccinates</td> <td>82,751</td> <td>1.12</td> </tr> <tr> <td colspan="3"><b>Site 2</b></td> </tr> <tr> <td>Control</td> <td>244,840</td> <td>0.48</td> </tr> <tr> <td>Control</td> <td>209,697</td> <td>0.30</td> </tr> <tr> <td>Control</td> <td>90,792</td> <td>0.28</td> </tr> <tr> <td>Vaccinates</td> <td>238,848</td> <td>0.33</td> </tr> </tbody> </table> <p>No adverse events were observed.</p>				Number placed	Mortality %	<b>Site 1</b>			Control	75,634	0.66	Control	107,587	0.88	Control	88,553	0.88	Vaccinates	82,751	1.12	<b>Site 2</b>			Control	244,840	0.48	Control	209,697	0.30	Control	90,792	0.28	Vaccinates	238,848	0.33
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